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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/601,841

06/23/2003

Andrew D. Roberts

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23524 7590 05/17/2006

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EXAMINER

PERREIRA, MELISSA JEAN

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/601,841	Applicant(s) ROBERTS ET AL.	
	Examiner Melissa Perreira	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/23/03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruth et al. (*J. of Rad. and Nuclear Chem.* **1996**, 203, 457-469) in view of Roberts et al. (*Res. and Indus.* **1999**, 1006-1009, No 475).

Ruth et al. (*J. of Rad. and Nuclear Chem.* **1996**, 203, 457-469) teaches of the ^{18}F - fluorination of alkanes via displacing either a halogen or sulfonate substituent with a soluble and reactive form of ^{18}F -fluoride and specifically provides a structure of 1-bromo-3- ^{18}F fluoropropane (p 464) for use as a PET imaging agent. Ruth et al. (*J. of Rad. and Nuclear Chem.* **1996**, 203, 457-469) does not teach of an ^{17}F labeled alkane having 2 or more carbon atoms. Roberts et al. (*Res. and Indus.* **1999**, 1006-1009, No 475) teaches of an ^{17}F labeled fluoromethane generated from ^{17}F and CH_3Br that shows great promise as an improved tracer for regional cerebral blood flow measurements with PET. The advantages of using an ^{17}F labeled fluoroalkane over an ^{18}F labeled fluoroalkane is that the short half life and rapid decay of ^{17}F makes it possible to collect images in a shorter time period (6 sec as opposed to 12 sec) and provides for greater temporal resolution. At the time of invention it would have been obvious for one ordinarily skilled in the art to use ^{17}F as the radiolabel in the PET imaging agents

disclosed by Ruth et al. (*J. of Rad. and Nuclear Chem.* **1996**, 203, 457-469) to gain the advantage of this label as taught by Roberts et al. (*Res. and Indus.* **1999**, 1006-1009, No 475).

It is respectfully pointed out that instant claims 4 and 5 are product-by-process claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pike et al. (*Drug Metab. Dispos.* **1995**, 23, 832-839) in view of Roberts et al. (*Res. and Indus.* **1999**, 1006-1009, No 475) and/or Mulholland et al. (*J. Nuc. Med.* **1987**, 8, 1082, posterboard 899).

Pike et al. (*Drug Metab. Dispos.* **1995**, 23, 832-839) teaches of an ^{18}F -labeled HFA134a (1,1,1,2-tetrafluoroethane) as a sensitive whole-body gamma-counting technique to measure the whole-body and regional absorption, distribution, and retention of HFA134a after administration in humans by single-breath inhalation but does not teach an ^{17}F labeled 1,1,1,2-tetrafluoroethane. Roberts et al. (*Res. and Indus.* **1999**, 1006-1009, No 475) teaches of an ^{17}F labeled fluoromethane generated from ^{17}F and CH_3Br that shows great promise as an improved tracer for regional cerebral blood flow measurements with PET. Mulholland et al. (*J. Nuc. Med.* **1987**, 8, 1082,

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posterboard 899) teaches of the synthesis of ^{17}F by the $^{16}\text{O}(\text{p},\text{n})^{17}\text{F}$ reaction and ^{17}F fluoromethane via the Hunsdiecker-like decomposition of ^{17}F acetyl hypofluorite and by passage of ^{17}F gas through CH_3HgCl . The advantages of using an ^{17}F labeled fluoroalkane over an ^{18}F labeled fluoroalkane is that the short half life and rapid decay of ^{17}F makes it possible to collect images in a shorter time period (6 sec as opposed to 12 sec) and provides for greater temporal resolution. At the time of the invention, it would have been obvious to one ordinarily skilled in the art to combine the information taught by Pike et al. (*Drug Metab. Dispos.* **1995**, 23, 832-839), Roberts et al. (*Res. and Indus.* **1999**, 1006-1009, No 475) and/or Mulholland et al. (*J. Nuc. Med.* **1987**, 8, 1082, posterboard 899) to generate a 1,1,1,2-tetrafluoroethane with at least one of the F atoms being an ^{17}F with a reasonable expectation of success.

Conclusion

No claims are allowed at this time.

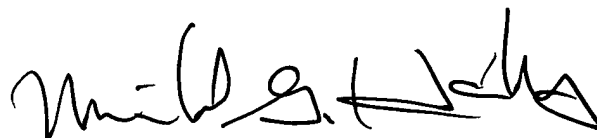
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MP May 5, 2006

A handwritten signature in black ink, appearing to read "Michael G. Hartley", with a stylized flourish at the end.

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER